

OCT 24 2001

# BIONOSTICS

## 510(k) Summary\*

K013147

(a) (1) **Submitter's name, address**  
Bionostics, Inc.  
7 Jackson Road  
Devens, MA 01432

**Contact Person**  
Kathleen Storro  
Director, QA & Regulatory Affairs  
(978) 772-7070 x 220

**Date of preparation of this summary:** 18 September 2001

(2) **Device trade or proprietary name:** Glucose Control Solution for  
TheraSense FreeStyle® BGM

**Device common or usual name or classification name:**

Multi Analyte Control Solution, All Types (Assayed and Unassayed)

<u>PRODUCT NOMENCLATURE</u>	<u>CLASSIFICATION</u>		
	<u>NUMBER</u>	<u>CLASS</u>	<u>PANEL</u>
SINGLE ANALYTE CONTROL SOLUTION	862.1660 75 JJX	I	CHEMISTRY

(3) **Substantial Equivalence**

Glucose Control Solution for TheraSense FreeStyle is substantially equivalent in function, safety and efficacy to currently marketed devices produced by Bionostics. In example:

**Comparison Glucose Control Solution for TheraSense FreeStyle to predicate devices for substantial equivalency**

Characteristic	Predicate Devices		Modified Device
Name:	Multi-Meter Glucose Calibration Verification Material	Glucose Control Solution for LifeScan FastTake	Glucose Control Solution for TheraSense FreeStyle
510(k), Date:	K012430, 08/27/01	K000318, 02/28/00	
Number of levels:	5	1	3
Analytes:	Glucose	Glucose	Glucose
Container:	plastic bottle	plastic bottle	plastic bottle
Fill volume:	4 mL	4 mL	4 mL
Color:	red	red	red
Matrix:	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.

\* This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

- (4) **Description of the new device**  
**Glucose Control Solution for TheraSense FreeStyle** is a three-level, viscosity-adjusted, aqueous liquid glucose control solution. **Glucose Control Solution for TheraSense FreeStyle** provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip.
- Glucose Control Solution for TheraSense FreeStyle** contains glucose values at three points within the reportable range and verify performance of the TheraSense FreeStyle BGM.
- Glucose Control Solution for TheraSense FreeStyle** is a non-hazardous aqueous solution containing no biological materials.
- (5) **Intended use of the device**  
**Glucose Control Solution for TheraSense FreeStyle** is intended to be used to monitor and evaluate the analytical performance of the TheraSense FreeStyle BGM.
- (6) **Technological characteristics of the device.**  
This material consists of viscosity-adjusted, aqueous glucose control solutions prepared in three specific glucose concentrations. The solutions have been optimized to simulate the response of whole blood on the TheraSense FreeStyle BGM system.
- (b) (1) **Summary of non-clinical tests submitted with the premarket notification for the device.**  
Tests were conducted to verify specific performance requirements:
- a) Closed bottle stability
  - b) Stability after opening
  - c) Correlation to gravimetric D-glucose
  - d) Test precision and range
- (b) (2) **Summary of clinical tests submitted with the premarket notification for the device.**  
N/A
- (b) (3) **Conclusions drawn from the clinical and non-clinical trials.**  
Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

OCT 24 2001

Ms. Kathleen Storro  
Director, QA and Regulatory Affairs  
Bionostics, Inc.  
2 Craig Road  
Acton, MA 01720

Re: k013147  
Trade/Device Name: Glucose Control Solution for TheraSense FreeStyle  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality Control Material (Assayed and Unassayed)  
Regulatory Class: I, reserved  
Product Code: JJX  
Dated: September 18, 2001  
Received: September 20, 2001

Dear Ms. Storro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

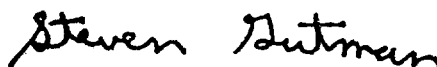
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

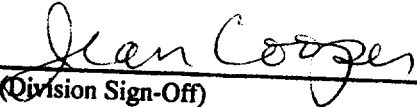
510(k) Number: **K013147**

Device Name: **Glucose Control Solution for TheraSense FreeStyle**

**Indications for Use:**

**Glucose Control Solution for TheraSense FreeStyle Blood Glucose Monitoring System is intended for use to verify the performance of the FreeStyle BGM System at multiple glucose levels within the reportable range. The Glucose Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home.**

**For *In Vitro* Diagnostic Use**

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K013147

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☒

(Optional Format 1-2-96)